K083139

2. 510(k) Summary

NOV 2 5 2008

Company Name:	Cardiovascular Systems, Inc. 651 Campus Drive St. Paul, MN 55112	
Contact:	David Brooke Sr. Regulatory Manager	
Phone:	(651) 259-1630	
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Summary Date:	November 14, 2008	
Trade Name:	Vipersphere™ PTA Balloon Catheter	
Common Name:	Peripheral Angioplasty Balloon Catheter	
Classification Name:	Percutaneous Catheter (21 CFR 870.1250; Product Code: LIT)	
Predicate Device:	510(k) Number: Manufacturer: Trade Name:	K993913 Infinity Extrusion & Engineering TRUE PTA Balloon Catheter
	510(k) Number: Manufacturer: Trade Name:	K053116 Boston Scientific Sterling PTA Balloon Catheter
	510(k) Number: Manufacturer: Trade Name:	K971010 Cordis Corporation Savvy PTA Balloon Catheter
	510(k) Number: Manufacturer: Trade Name:	K052791 ev3 Amphirion PTA Balloon Catheter

2.1 Description of Device

The Vipersphere™ PTA balloon catheter is a standard percutaneous transluminal angioplasty balloon catheter intended for use in the peripheral vessels.

The Vipersphere™ PTA balloon catheter is provided in an over-the-wire configuration with a standard y-adapter on the proximal and a hydrophilic coating balloon on the distal end. The multiple balloon sizes are available with diameter of 2.0mm to 5.0mm and lengths of 10cm, 15cm and 20cm.

2.2 Intended Use

The ViperSphere PTA balloon dilatation catheter is intended to dilate stenoses in peripheral arteries including the iliac, femoral, popliteal, and infra-popliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

2.3 Conclusions

The Vipersphere™ PTA balloon catheter is substantially equivalent to the predicate devices. Laboratory test data were provided to support the safety and effectiveness of the Vipersphere PTA balloon catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 25 2008

Cardiovascular Systems, Inc.
c/o Mr. Mark Job
Reviewer
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K083139
Vipersphere™ PTA Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 17, 2008
Received: November 18, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1. Indications for Use Statement

510(k) Number: K083139

Device Name: Vipersphere™ PTA Balloon Catheter

Indications for Use:

The ViperSphere PTA balloon dilatation catheter is intended to dilate stenoses in peripheral arteries including the iliac, femoral, popliteal, and infra-popliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Prescription Use _X_ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vollmer

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K083139